# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/500,454 | 02/08/2005 | Monique Berwaer | 2004_0980A | 2307 |

513 7590 09/01/2005

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

| EXAMINER | |
|---|---|
| SILVERMAN, ERIC E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | |

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/500,454 | BERWAER ET AL. | |
| | Examiner | Art Unit | |
| | Eric E. Silverman, PhD | 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6-30-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.



5.00

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Regarding claim 4, the phrase "can be" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guy et al. (US 3,906,086) in combination with Kreutner et al. (US 5,869,479).

Guy teaches a double layer tablet for administration of a medicament, wherein the tablet is formulated to provide both immediate release and sustained release of said medicament (column 5, lines 43 – column 6, line 5). Guy further teaches that this type of double-layered tablet is conventional in the art, and that this type of controlled release is known in the art o be desirable for certain purposes (ibid.).

Guy does not teach using efletirizine in this type of formulation.

Kreutner teaches efletirizine is a known medicament that can be formulated in tablets (see claim 4 and example 8).

Thus it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use efletirizine in a double tablet formulation that allows for both immediate and sustained release of the medicament. The motivation to do so is provided by Guy, who teaches that this type of formulation is known to be useful in the pharmaceutical arts. Since a double tablet formulation that allows for both immediate and sustained release of the medicament is taught to be conventional in the pharmaceutical arts, the artisan would have a reasonable expectation of success in performing such manipulations. The expected result would be a efletirizine formulation that allowed for both sustained and immediate release. This is the same result disclosed by Applicant, thus Applicant's results are not unexpected.

Instant references do not mention specific amounts of medicament to be used. Nonetheless, determining optimal dosages is within the purview of the skilled artisan. A

person of ordinary skill in the art would be aware that the amounts of the individual dosages, the frequency at which said dosages must be taken, and the total number of doses will naturally vary according to the age, gender, weight, severity and type medical condition, the type of medicament, and other pertinent factors pertaining to the patient to whom the medicament will be administered. In order to account for these variations, a person of ordinary skill in the art would be motivated to provide for a wide variety in the specific amounts of medicaments, including variety in the total number of doses, amount of medicaments in each dose, and the frequency at which the doses must be taken in order to accommodate a wide variety of patents with a wide variety of dosing needs. In general, changing the specifics of dosing, absent an unexpected result, will not raise a claimed invention over the prior art.

Examiner notes that recited "can be" in claim 4 means that the recited "administered in a single daily dose" is optional, and is not a structural limitation of the claim.

Examiner further notes that since these references do not mention basifying agent, such is presumed to be absent and thus the limitations of claim 6 are also taught by the combination of these references.

Claims 1 – 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al (US 4,464,375) in combination with Kreutner.

Sunshine teaches a composition that allows for both the extended and immediate release of an active agent (column 16, lines 16-26). Sunshine further teaches the active agent in a range that is appropriate for that specific active agent, and motivates using

such dosage form by noting that the same is advantageous when long-acting drugs are employed.

Sunshine does not teach the use of efletirizine in the dosage form.

The teachings of Kreutner are discussed above.

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use efletirizine in a formulation that allowed for both sustained and immediate release, thus rendering the entire invention as a whole prime facie obvious. The motivation to combine references is given by Sunshine, who teaches that it is advantageous to use a dosage form that allows for sustained and immediate release when long-acting formulations are desired. The expected result would be a formulation that had a long-acting effect, wherein efletirizine was released immediately and over a prolonged time period.

Instant references do not mention dosing, however, determining the optimum dose to obtain a desired therapeutic effect is within the skill of the artisan, and the motivation is to obtain maximum therapeutic effect. A person of ordinary skill in the art would be aware that the amounts of the individual dosages, the frequency at which said dosages must be taken, and the total number of doses will naturally vary according to the age, gender, weight, type of medicament, severity and type medical condition, and other pertinent factors pertaining to the patient to whom the medicament will be administered. In order to account for these variations, a person of ordinary skill in the art would be motivated to provide for a wide variety in the specific amounts of medicaments, including variety in the total number of doses, amount of medicaments in

each dose, and the frequency at which the doses must be taken in order to accommodate a wide variety of patents with a wide variety of dosing needs. Sunshine teaches the dosages to be utilized for caffeine, which is the beneficial agent in that invention, but the artisan would recognize that the optimum dosage for efletirizine is not the same, and would determine said optimum dosage without undue experimentation, and with a reasonable expectation of success.

Claims 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sunshine et al (US 4,464,375) in combination with Kreutner as applied to caims 1 – 5 above, and in further view of Guy.

The teachings of Sunshine and Kreutner are discussed above. These references do not teach a double-layer tablet.

Guy teaches a double-layer tablet, and that such is a conventional means to deliver a medicament so that the medicament may have two different release profiles, such as immediate release in combination with prolonged release (column 5, lines 43 – column 6, line 5).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use a double-layered tablet as the dosage form for the controlled-release dosage form that is rendered obvious by Sunshine and Kreutner. A person of ordinary skill in the art would be motivated to do so because such is a typical means in the art for making such types of dosage forms. This amounts to a common manipulation in the art. Thus, a person of ordinary skill in the art would have a reasonable expectation of success at such manipulations.

***Conclusion***

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 9:00am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Eric Silverman, PhD
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600